March 12, 1997

EPA-SAB-CASAC-LTR-97-004

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Subject: Evaluation of Research Needs for the Particulate Matter National Ambient Air Quality Standards (NAAQS)

Dear Ms. Browner:

The Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB), supplemented by a number of expert consultants (together referred to as the "Panel"), reviewed the two draft documents, *Particulate Matter Research Needs for Human Health Risk Assessment* (EPA, 1996a) and *Particulate Matter Research Program Strategy* (EPA, 1996b) at a public meeting in Chapel Hill, NC on November 18 and 19, 1996. At that meeting and in subsequent written comments that were provided to EPA staff (hereafter referred to as the "Staff"), the Panel made numerous recommendations for improving the documents. This letter is a summary of the Panel's key comments and conclusions. Staff is referred to the transcript of the meeting and to individual members' comments for details and issues beyond this summary.

The Panel commends the Staff for developing these important documents, and notes that the review drafts represent significant steps toward setting the stage for the research that is critical to resolving present uncertainties about the health impacts of particulate matter (PM). In its past reviews of the Particulate Matter Criteria Document and Staff Paper, the Panel repeatedly asserted its strong recommendation that critical PM research be identified and a strategy for its accomplishment be developed. With revision, these documents will set forth a framework from which more detailed plans can be developed by EPA and other stakeholder organizations.

1. Particulate Matter Research Needs for Human Health Risk Assessment

The document is of sufficient length and complexity that it would benefit from addition of an Executive Summary and a final section in which Staff presents its summary and conclusions, as well as reorganization to give greater recognition to phased needs and goals.

The comprehensiveness of this document is both a strength and weakness. In its present form, it is an encyclopedic compilation of PM research topics, but it lacks sufficient focus to present a clear view of the most important research needs. The document's utility suffers from its failure to clearly place PM research needs in the context of the present large uncertainties in assessing the health risks from inhaled PM, and thus in setting the form and level of PM NAAQS. Beginning with a risk assessment framework would resolve many of the specific criticisms raised in individual Panel members' comments. A useful approach would be to begin with a framework consisting of the key steps in health risk assessment and standard setting. The key uncertainties presently limiting accomplishment of each step could then be listed in summary form and then summary statements of the information needed to reduce the key uncertainties could be listed. With this structure as a prologue, the most important research and the research approaches likely to be most productive could be described. This risk-based framework should look forward to the next review of the PM NAAQS; however, a commitment to research over a longer period (e.g., 10 - 15 years) is also needed. The likelihood of having a significant impact on the regulatory decision in 2001 is a useful criterion for prioritizing much of the proposed research. The document would be much improved by summarizing the above information in tabular or figure form.

Critical to the above process is an accurate portrayal of the nature and magnitude of present uncertainties. Several Panel members expressed concern that the present draft does not reflect present uncertainties accurately. The Panel noted that the present draft conveys the notion that the direct causality of PM, and especially $PM_{2.5}$, in the health effects observed by epidemiology is established. While the Panel agrees that present evidence warrants concern and most members support implementation of a fine particle standard, the Panel urges that it be explicitly stated that the causality of $PM_{2.5}$ has not been clearly established. In this and previous meetings, the Panel has noted a range of important uncertainties. For example, in its March 15, 1996 letter of closure on the draft PM Criteria Document (SAB, 1996a), CASAC noted uncertainties concerning the relationship between area monitoring data and personal exposure, and concerning the suitability of $PM_{2.5}$ as the best surrogate for the causative agent(s). CASAC also noted that some reviews of the epidemiological database indicated that the health effects could not be unambiguously associated with

PM. In its June 13, 1996 letter addressing the PM Staff Paper (SAB, 1996b), CASAC offered a range of views about the justification for, and most appropriate level of, a $PM_{2.5}$ standard, and listed numerous specific uncertainties that need to be resolved.

This review of research needs requires greater consideration of the magnitude of funding required to fill the most critical information gaps. Much of the proposed research is feasible, but cannot be conducted within the level of funding directed toward PM research in the present or recent fiscal years. The continued failure to fund PM research at a level commensurate with its importance is a critical gap in EPA's research strategy. The document does not portray the cost of research required to address even the most key uncertainties. Describing the approximate costs and time lines would place PM research needs in a budget context and could facilitate discussion of sharing of costs among agencies and other sponsors.

The review of research needs would also benefit from more consideration of the technical practicality and time requirements of conducting the proposed research. As noted in individual members' comments, some of the research suggested is not presently feasible for technological reasons. The time required to fill critical information gaps is not portrayed. The document would benefit from the placement of research in a time context with the next review of the PM NAAQS as a focal point. Although work on many issues must continue beyond that point, this benchmark would engender a realistic expectation of the work that could be accomplished by then, and as noted earlier, would help with prioritization.

There should be greater emphasis on resolving uncertainties about the long-term effects of PM. Additional attention should be focused on long-term effects, such as life shortening or progressive disease. Accompanying data are needed on long-term PM levels, trends, and characteristics, as well as levels of other pollutants. The Panel felt that there was little need for documenting additional examples of associations between short-term increases in PM and health effects using the same approaches as in the past. There is a need for new data sets providing improved understandings of the individuals incurring short-term effects and the physical-chemical nature of the PM to which they were exposed, and for alternate data analysis techniques.

The Panel noted a lack of emphasis on retrospective research to determine the effectiveness with which reductions in PM and other pollutants reduce adverse health effects. Many of the data cited as demonstrating the health effects of current concern were collected 10-15 years ago. The downward trend in ambient PM should provide opportunities to demonstrate an associated health benefit, and it might also be possible

to follow implementation of specific source controls in some locations with studies to detect improvements in health indices thought to be associated with PM. The Panel appreciates the difficulty, pointed out by Staff, of detecting reductions in risks associated with reductions of PM in view of their probable small magnitude and numerous confounding factors. The Panel, however, would also remind the Agency that it is precisely these health risks in the presence of confounding influences and other uncertainties that give rise to the proposed change in the PM standard. Demonstration of an association between reductions of PM and adverse health outcomes would support causality.

The need for cross-disciplinary and international interactions is not adequately emphasized. The efforts of atmospheric scientists, laboratory researchers, clinical researchers, and epidemiologists will be required to resolve several of the uncertainties, and consideration should be given to providing a framework for integrating these efforts. There should be mention of the need for research training with a focus on cross-disciplinary perspectives and collaborations. Collaboration of EPA and its supported researchers in international efforts, for example with the "Air Pollution and Health: European Project", should also be emphasized.

In his October 28, 1996 letter (EPA, 1996c), Dr. Lester Grant charged the Panel with providing feedback on three issues (identified as a), b), and c) below). In aggregate, the above comments and the comments of individual Panel members, submitted to Staff, address those issues. We provide the additional following comments.

a) Are the key questions/issues identified as needing to be addressed on the mark? Has too much or too little emphasis been placed on one or another of the key questions? Do other key questions/issues need to be added?

(1) Several Panel members noted that the section containing key questions could be improved by stating the key questions in summary form and eliminating, or summarizing more succinctly, the "subquestions".

(2) Less emphasis should be given to short-term epidemiology and greater emphasis should be given to long-term epidemiology and associated exposure characterization.

(3) In question 4.C and elsewhere, eliminate the "live" and "dead" particle terminology.[1]

(4) Question 8 is framed more as an operational issue than a research need. It is probably best stated as a subquestion under questions 7 or 9.

b) Are the research needs identified subsequently in the document appropriate and adequately characterized? Are there others that need to be added?

There was no consensus that major research needs were overlooked. Some members noted the need for an improved understanding of PM concentrations that might be considered "background", or representative of broader rural and semirural areas than present monitoring sites allow. The individual comments contain numerous additional suggestions for improving the scope and description of the needs. Although few of the comments of individuals were mutually exclusive, their diverse nature makes it impractical to summarize them in this letter.

c) Can the Committee assist EPA in terms of helping to prioritize the stated research needs? Within given categories (e.g., exposure, health, etc.) and/or across categories?

An exhaustive prioritization of the needs listed in this document was not undertaken by the Panel; priorities were addressed in greater detail in review of the Research Strategy document. While Staff is encouraged to consider comments of individual Panel members on priorities within different research topics, the following topics were generally considered to be of high priority:

(1) Effects of long-term exposures and relative contributions of short-term spikes and cumulative exposures to long-term health outcomes.

(2) Mechanisms by which PM could contribute to life shortening, daily mortality, and morbidity

[1] "Dead" particles are either laboratory particles or collected, dried and resuspended ambient PM. "Live" particles are ambient air or generated in smog chambers that are in equilibrium with water vapor, gaseous pollutants and dissolved components.

(3) Linkages between PM data from area monitors and personal exposures

(4) PM classes and physical-chemical characteristics associated with different health effects, and

(5) extent to which PM causes health effects independently of other pollutants.

2. Particulate Matter Research Program Strategy

The Panel was charged by Staff in Dr. Grant's October 28, 1996 letter (EPA, 1996c) to provide feedback in the following two areas:

a) Review and comment on the research questions and issues EPA has selected to focus on and the approaches EPA is planning to use to address those questions/issues.

b) Comments and recommendations regarding relative priorities for the various stated research areas/directions.

The following comments address these and other issues in areas for which opinion could be generalized. Staff is encouraged to review the wide range of additional comments contained in the written comments of individual Panel members, which have been submitted to Staff.

This document is presented as a statement of EPA strategy for PM research, but it falls short of defining and defending a strategic action plan. Like the Research Needs document, this draft does not provide an adequate risk assessment framework for identifying and prioritizing research and for allocating resources to the effort. The strategy should flow from the Research Needs document by beginning with an expression of key research needs arising from present uncertainties in setting the PM NAAQS, and should be targeted toward improving the Agency's position at the next review. This structure would help resolve the inadequate explanation in the present draft of the basis for ranking. It is not clear which group, or by what process, the present ranking and strategy were developed. The present draft does not place its strategy in the context of research under way or proposed in other offices within the Agency, in other Agencies and organizations, or in other countries. It is not clear, for example, if this is an Agency-wide strategy or just a strategy for ORD.

The critical issues of the allocation of resources to PM research and the progress likely to result from those expenditures are missing from the discussion of strategy. Oral presentations by Staff indicated that a total of $20 million annually was projected for EPA PM research, and that represents approximately 0.3% of EPA's budget. Moreover, it appears that only approximately 5% of EPA's research staff is focused on PM issues. The Panel was unanimous in expressing its strong concern that this level of funding and staffing falls far short of the resources needed to make progress commensurate with the health and economic implications of estimated PM effects and costs of controls. At this rate, support over even the five-year period between PM NAAQS reviews would fall below annual expenditures by EPA and other Agencies on issues having lesser estimated health and economic impacts. As a related issue, EPA needs to highlight linkages to other programs within the Agency and to efforts in other agencies that, in aggregate, constitute the nation's effort to understand PM and its effects.

This document shares with the Research Needs document the characteristic of overstating the certainty of the causality of PM in the health effects observed by epidemiology, and especially the level of certainty concerning the causality of $PM_{2.5}$ in the adverse effects. Indeed, because the magnitude of this uncertainty underlies and supports the priority of many of the strategic research goals, the uncertainty should be emphasized rather than minimized.

Because the human health research priorities should flow from the information needs described in the Research Needs document, health effects issues that are not listed in that document should not be raised anew in this one. Examples of new issues, such as the mention of altitude as a variable of concern, are contained in individual Panel members' comments.

The key questions beginning on page 14 should be portrayed more clearly. They should be organized around the framework of risk assessment, should be stated more succinctly, and should be followed by a succinct statement of the basis for their importance. If they are to be retained, the subheadings under each key question should be prioritized.

Several Panel members commented that the structure of the ranking criteria beginning on page 19 was not sufficiently focused. An example of a more focused approach might be: a) likely impact on reducing uncertainties key to consideration of the PM NAAQS; b) probability of success within technology and resources available; and c) likelihood of creating knowledge also useful in other areas.

The core issue of the document is the prioritization of research topics. As might be expected from a Panel consisting largely of senior researchers from different disciplines, a range of diverse and sometimes conflicting opinions was offered regarding research priorities. This summary does not attempt to portray fully this range of opinion; Staff is encouraged to examine the written comments of individual Panel members.

There was consensus that epidemiological research on links between long-term exposure to PM and life shortening and other long-term health effects was among the highest priorities. Research on short-term effects should focus on refining our understanding of exposure-dose-effects relationships. Priority should be given to epidemiological studies of either type which provide the ability to examine linkages between health effects and personal exposures to physical-chemical subclasses of PM. When known, the nature and dose-response relationship of the effects of individual compounds in pure form might provide a point of reference useful for judging the plausibility of effects estimated for those compounds encountered as constituents of PM.

There was also consensus that laboratory and clinical research exploring potential mechanisms of response to PM was among the highest priorities. Greatest value was placed on research exploring associations between physical-chemical PM characteristics and response pathways and potency. High value was also placed on studies exploring the existence and nature of responses at environmentally-relevant doses of PM.

Research providing a better understanding of personal exposure, and especially of individuals thought to be most susceptible, was given high priority.

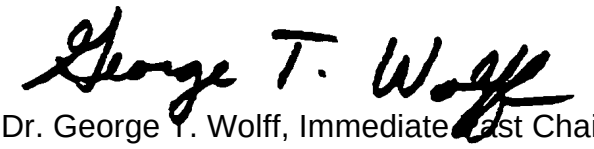
Beyond the above priorities, opinion was mixed and defied straightforward summary. There was mixed enthusiasm for atmospheric modeling and characterization of source emissions. Studies of the dosimetry of inhaled particles in normal subjects was not given strong support, although it was agreed that present dosimetry models could benefit from a better understanding of particle deposition and clearance in abnormal lungs. There were mixed views regarding the priority of developing tools for market-based control approaches. Some members favored conducting research to improve market-based approaches. Others warned that not all $PM_{2.5}$ species are equipotent and that such approaches must be informed by an understanding of the relative contributions of different physical-chemical classes of PM within size ranges. Staff is advised to weigh these issues in view of individual members' comments.

3. Summary

The Panel commends Staff for initiating the strategic planning which resulted in these draft documents, and encourages Staff to undertake the revisions necessary for the documents to serve as a solid foundation for EPA's PM research program. These documents can play a critical role in EPA's ability to fulfill its mission to protect the public health from airborne pollutants. The Panel recognizes that some of the recommended changes will require significant effort and additional resources, but believes that the effort will be well-placed in improving EPA's PM research program and the benefits attributable to the program's findings. In view of the importance the Panel attaches to the PM research program and thus the proposed revisions, the Panel looks forward to the opportunity to review the revised documents. The Panel appreciates the opportunity to provide comments on these documents, and looks forward to completion of this important effort. We look forward to your response to our advice.

Sincerely,

/signed/
Dr. Joseph L. Mauderly, Chair
Clean Air Scientific Advisory Committee



Dr. George T. Wolff, Immediate Past Chair
Clean Air Scientific Advisory Committee

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